meaning of the term growth factor is specific to polypeptides and that Applicant's definition, which include cells as being encompassed by such a term is outside such ordinary and customary meaning. Applicant agrees with the Examiner that polypeptides are a known sub-class or species of growth factors but respectfully points out that within the context of the invention that the genus growth factor is intended to include sub-groups and species in addition to polypeptides, which sub-groups and species are described in the subject application.

There is a body of law that supports the proposition that an Applicant is permitted to be its own lexicographer. Perforce, it is proper to look to the subject specification as a dictionary, which explains the invention and defines the term growth factor. See Autogiro Co. of Am. v. United States, 384 F.2d 391, 397 (Ct. Cl. 1967); Intellical v. Phonometrics, Inc., 952 F.2d 1384, 1388, 21USPQ 2d 1671, 1674 (Fed.Cir. 1992); Vitronics Corp. v. Conceptronics, Inc.; 90 F.3d 1576, 39USPQ 2d 1573, (Fed.Cir.1996); and Hockerson-Halberstadt, Inc. v. Avia Group Int'l., Inc., 222 F.3d 951, 955 (Fed. Cir. 2000).

The first paragraph of MPEP 608.01(o) states that:

> The meaning of every term used in any of the claims should be apparent from the descriptive portion of the specification with clear disclosure as to its import; and in mechanical cases, it should be identified in the descriptive portion of the specification by reference to the drawing, designating the part or parts therein to which the term applies. A term used in the claims may be given a special meaning in the description. No term may be given a meaning repugnant to the usual meaning of the term.

Applicant considers that the meaning to the term growth factor is clearly defined in the instant specification, and it is apparent that such meaning would be understood by persons in the medical arts. The definition states that "Growth factors can be utilized to induce the growth of "hard tissue" or bone and "soft tissues" like ectodermal or mesodermal tissues." The definition

then proceeds to list a large number of compositions and living organisms, which promote the growth of such tissue. Growth factor is defined in the Medical Dictionary of Merriam-Webster found on MEDLINE Plus Health Information (please see Exhibit I in this regard) as comprising "a substance (as a vitamin B_{12} or an interleukin) that promotes growth and especially cellular growth." Applicant submits that the meaning of growth factor is: (1) apparent from the specification; and (2) consistent with the meaning ascribed by the Merriam-Webster Medical Dictionary. Thus, Applicant clearly has not provided a meaning for growth factor that is repugnant to the usual meaning of such term and, accordingly, compliance with MPEP 608.01(o) is evident.

The Examiner's attention is further specifically directed to Applicant's extrinsic evidence in the form of two Declarations of medical experts, Dr. Richard Heuser and Dr. Andrew E. Lorincz that is being submitted concurrently with this Amendment. Both Declarants state their belief that the respective definitions of Applicant and the above-mentioned Merriam-Webster Medical Dictionary are consistent and have adopted Applicant's definition for purposes of the respective Declarations. Such Declarations provide additional evidence and support for Applicant's position.

Finally, Applicant also points out that the Patent and Trademark Office has previously approved the use of Applicant's definition of growth factor in granting U.S. Patent No. 5,759,033 (Please see Exhibit II in this regard). The Examiner is referred to column 13, line 31, through column 14, line16 and claims 3-26 wherein growth factor is used as a genus for many species. The grant of such patent provides further extrinsic evidence that the meaning of the term is apparent in the art.

The Examiner is respectfully requested to favorably consider the above extrinsic evidence and remarks because the requisite certainty exists in being able to construe the claims in light of

the specification.

It is appreciated that the Examiner's restriction requirement (Paper No. 5) did not include an action on the merits. However, Applicant has submitted the following information to support that the elected and newly presented claims fully comply with the technical requirements of 35 U.S.C. 101 and 112. Applicant believes that such submission will serve to advance the prosecution of the application.

Applicant has submitted four publications in the above-mentioned IDS that support operability of the claimed invention. The publications disclose use of a growth factor to grow new muscle in a human heart. The Examiner is respectfully requested to consider these publications with regard to the operability of the newly submitted claims.

While the above-discussed publications speak for themselves, Applicant obtained Declarations of two experts in the medical arts; namely, Drs. Heuser and Lorincz. The experts all opined that the invention described and claimed in the instant application is operative in view of the information contained in the publications. Applicant believes that the fact that experts from different medical backgrounds, i.e., cardiovascular and genetics, reached the same conclusion further strengthens Applicant's operability evidence. The Examiner is respectfully requested to consider the two Declarations.

It is important to note that the first paragraph of 35 U.S.C. 112 requires nothing more than objective enablement, and it is of no importance whether such teaching is set forth by use of illustrative examples or by broad terminology. As a general matter, an application disclosure which contains a teaching of how to make and use the invention in terms which correspond in scope to those used in describing the invention sought to be patented is considered to be in compliance with the enabling requirement of the statue. In re Marzocchi, 58 CCPA 1069, 439 F.2d 220, 169 USPQ 367, 369-370 (1971). Further, "Section 112 does not require that a

specification convince persons skilled in the art that the assertions therein are correct. In re Robins, 429 F.2d 452, 166 USPQ 552 (CCPA, 1970) supra". [Emphasis added.]

Further, that the specification provides sufficient enablement is compelled from a reading of the above-mentioned Heuser and Lorincz declarations. Each of the two declarants, despite having different medical backgrounds, stated their opinion that one skilled in the medical arts, armed with the knowledge contained in the instant application, would be able to practice the invention set forth in the claims without need for resorting to undue experimentation.

Applicant provisionally elected, with traverse, to prosecute the claims of the Group 79 invention, i.e., claims 204 and 205. It is believed that new claims 236-253 would also fall under the Group 79 invention, and thus should be examined along with the elected claims. Applicant's traverse also identified claims 206-211 as falling under the Group 79 invention. Thus, the Examiner is further requested to reconsider the restriction requirement and examine claims 204-211 and 236-253 on the merits.

Should the Examiner have any questions or require additional information or discussion to place the application in condition for allowance, a phone call to the undersigned attorney would be appreciated.

Respectfully submitted,

Date: June 17, 2003

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